

HERBAL COUGH DROP- menthol lozenge

Winco Foods LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Menthol 4.8 mg

Active ingredient (in each drop)

Menthol 4.8 mg

Purpose

Cough Suppressant/

Oral anesthetic

Uses temporarily relieves:

cough as may occur with a cold or inhaled irritants

minor sore throat

Warnings

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have

persistent or chronic cough such as occurs with smoking, asthma, or emphysema

cough accompanied by excessive phlegm (mucuc)

Stop use and ask doctor if

cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

sore throat is severe, or irritation, pain or redness lasts or worsens

sore mouth does not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

adults and children 6 years and over allow 2 drops to dissolve slowly in mouth one at a time. May be repeated every two hours as necessary by a doctor.

children under 6 years ask a doctor

Other information 17 calories per drop

Inactive ingredients:Caramel (color), corn starch, glucose syrup, herbal extract blend (elder flower, Horehound, Hyssop, Lemon Balm, Linden Flower, Marshmallow Root, Peppermint, Sage, Thyme, Wild Thyme), natural flavors, soybean oil and sucrose.

Questions? Call 1-800-824-1706 Monday - Friday 9am to 4pm EST



HERBAL COUGH DROP

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67091-312 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 4.8 mg |

Inactive Ingredients

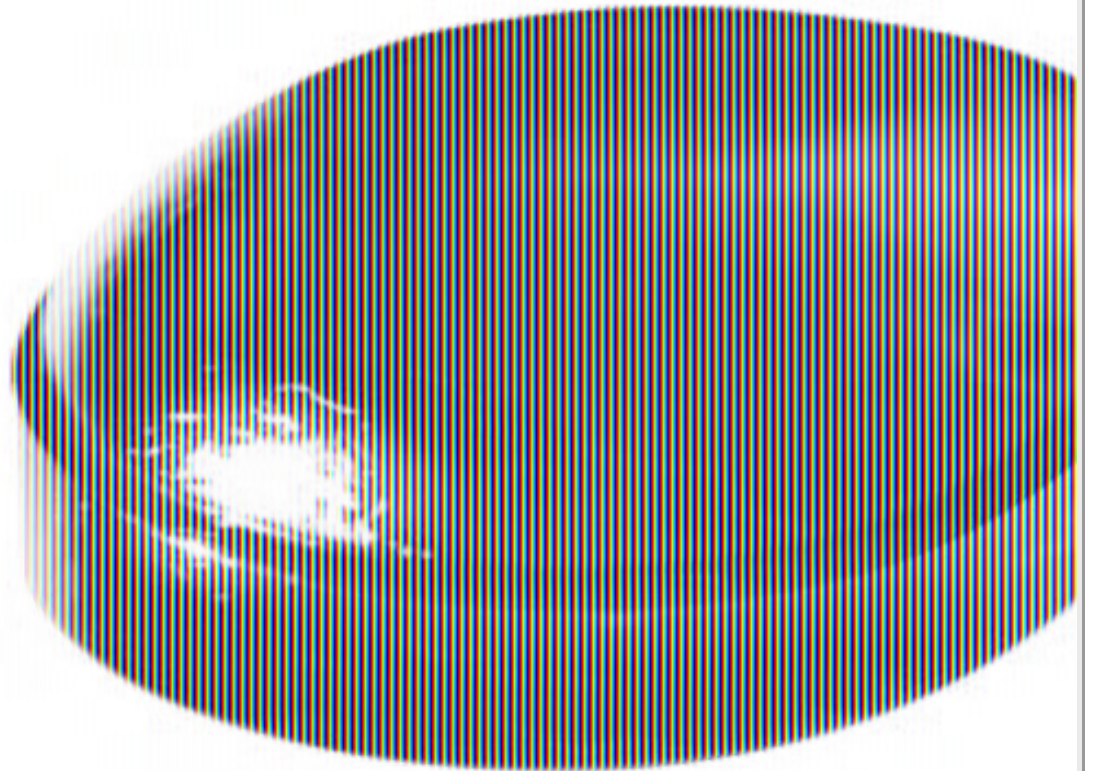
| Ingredient Name | Strength |
|--------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|--------------------------|---------------------|--------------------------|
| Color | brown | Score | score with uneven pieces |
| Shape | OVAL | Size | 17mm |
| Flavor | MENTHOL (Herbal Menthol) | Imprint Code | B |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:67091-312-21 | 21 in 1 BAG; Type 0: Not a Combination Product | 07/05/2017 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 07/05/2017 | |

Labeler - Winco Foods LLC (056098817)

Registrant - Bestco Inc. (002149136)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| BestCo Inc. | | 002149136 | manufacture(67091-312) |

Revised: 11/2021

Winco Foods LLC